IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SHIRLEY DAVILA, individually and pursuant to Pa.R.C.P. 2202(b) as Trustee Ad Litem for the Estate of JESSICA DIANE DAVILA, deceased	*	CIVIL ACTION
	*	NO. 12-CV-03962-TJS
Plaintiff,	*	
v.	*	
GENERAL NUTRITION CENTERS, INC., GNC HOLDINGS, INC., and USPLABS, LLC	*	
Defendants	*	

RESPONSE IN OPPOSITION TO PLAINTIFF'S MOTION TO REMAND FOR LACK OF SUBJECT MATTER JURISDICTION

Defendants, General Nutrition Centers, Inc., GNC Holdings, Inc. and USPlabs, LLC (hereinafter "Defendants") by and through their attorneys, Weber Gallagher Simpson Stapleton Fires & Newby, LLP, hereby submit the following Response in Opposition to Plaintiff's Motion to Remand for Lack of Subject Matter Jurisdiction and respectfully aver as follows:

1. Admitted, in part. Denied, in part. It is only admitted that Jessica Diane Davila died on November 14, 2011. The cause of death is at issue in this matter.

2. Admitted.

3. Denied as stated. The docket number is June Term 2012, Civil Action No. 2113.

4. Admitted.

5. Admitted.

6. Denied as a conclusion of law to which no response is required.

7. Denied as stated.

8. Denied.

9. Denied as stated.

10. Denied as stated.

11. Admitted.

12. Denied.

13. Denied.

14. Denied.

15. Denied.

16. Denied as stated. The decision of Judge Rufe in In re: Avandia Marketing, 2012 U.S. Dist. LEXIS 48319 (E.D.Pa. April 4, 2012) speaks for itself.

17. Denied as a conclusion of law to which no response is required.

18. Denied.

19. Denied.

20. Denied as a conclusion of law to which no response is required.

21. Denied.

22. Neither admitted, nor denied.

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Dated: August 20, 2012

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MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S MOTION TO REMAND

I. QUESTION PRESENTED

1. Whether this Court should exercise jurisdiction over a matter removed to federal court in which Plaintiff asks the court to determine whether the ingredients of a dietary supplement conform to the requirements of the Federal Food, Drug and Cosmetic Act?

Suggested Answer: Yes

II. INTRODUCTION

This matter arises from a wrongful death case brought by Plaintiff in the Court of Common Pleas of Philadelphia County alleging that Plaintiff's decedent was caused to die, in part, by consuming an ingredient in a dietary supplement manufactured and/or allegedly supplied by Defendants, called OxyELITE Pro.

Defendants filed a Notice of Removal on July 12, 2012 on the basis of federal question jurisdiction pursuant to 28 U.S.C. § 1331. Plaintiff filed a Motion to Remand on August 6, 2012.

This Court has jurisdiction over this matter as Plaintiff's claims turn on substantial issues of federal law.

III. FACTUAL BACKGROUND

Plaintiff's Complaint alleges that OxyELITE Pro ("the Product") was unlawfully marketed as a dietary supplement to consumers in violation of the Federal Food, Drug and Cosmetic Act, as amended by the Dietary Supplement Health and Education Act of 1994 ("FDCA").

Specifically, the Complaint states as follows:

41. "Defendant USP improperly claims that the PRO product is a legal dietary supplement."

42. "Contrary to the statement on the label of the PRO product, it contains a form of Dimethylamylamine known as DMAA"

43. "This product is a synthetic form that is illegal and unreasonably dangerous to consumers such as Jessica Diane Davila"

45. "The DMAA ingredient in PRO is manufactured synthetically, and therefore unlawfully on the market as an ingredient in OxyELITE Pro."

46. "PRO is an adulterated dietary supplement as that term is defined in the Food, Drug and Cosmetic Act."

47. "If DMAA is instead naturally extracted from a geranium plant, DMAA by virtue of its inclusion in the PRO product, makes the product nevertheless "adulterated" and therefore unlawfully on the market."

48. "Defendant USP's PRO product contains DMAA as a synthetic, as such it cannot be a constituent of a botanical."

49. "Regardless of the precise characterization of PRO, or the precise characterization of the DMAA contained in PRO, by engaging in the manufacturing, distribution, selling and/or supplying of PRO, ALL DEFENDANTS have violated relevant rules, regulations and/or statutes related to the Product.

See Plaintiff's Exhibit "A" at § § 41, 42, 43, 45, 46, 47, 48, 49.

The FDCA defines dietary supplements and describes "dietary ingredients" as a vitamin, mineral, herb or other botanical, amino acid, dietary substance for use by man to supplement the diet by increasing the total dietary intake, or concentrate, metabolite, constituent, extract, or combination of any dietary ingredient. 21 U.S.C. § 321(ff)(1). In fact, whether an ingredient, either natural or synthetic, is considered a "dietary ingredient" under the FDCA falls under the exclusive purview of the FDCA. Furthermore, the FDCA as amended by the Dietary Supplement Health and Education Act of 1994 regulates safety and labeling of dietary supplements.

Plaintiff's complaint specifically alleges that the Product contained a synthetic form of Dimethylamylamine, known as DMAA, which Plaintiff alleges made the product "adulterated" under the FDCA and thus allegedly unlawfully marketed as a dietary supplement. In doing so, Plaintiff has expressly raised the issue of whether the Product met the requirements of federal law, both in the Product's make-up and in Defendants' labeling of the product.

These issues are the subject of an administrative review currently being conducted by the U.S. Food and Drug Administration that was just commenced on April 24, 2012. See Exhibit "A". This administrative review process is ongoing as of this date with active involvement of Defendant USPlabs, four trade associations, two United States Senators, fourteen members of the House of Representatives, the FDA, and other companies and individuals in the dietary supplement industry. See Exhibit "B".

Defendants filed a Notice of Removal of this matter pursuant to 28 U.S.C. § 1331 as the court has federal question jurisdiction based on the Plaintiff's claims under the FDCA. In response, Plaintiff filed a Motion to Remand arguing that the product liability and breach of warranty claims sound solely in state law and that the case should be heard in state court. Plaintiff asserts that "[i]f USP and GNC manufactured, distributed, and sold PRO in violation of

any section of the FDCA, those violations will merely help Plaintiff to satisfy the elements of her state law claims."

Plaintiff's Motion to Remand ignores entirely Plaintiff's allegations regarding DMAA, which is the underlying basis of the Plaintiff's claims.

III. STANDARD OF REVIEW

28 U.S.C. § 1331 grants federal district courts original jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331. Federal question jurisdiction is usually invoked by plaintiffs pleading a cause of action created by federal law, but this Court has also long recognized that such jurisdiction will lie over some state-law claims that implicate significant federal issues. Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg., 545 U.S. 308, 312 (2005); see also Smith v. Kansas City Title & Trust Co., 255 U.S. 180 (1921) and Hopkins v. Walker, 244 U.S. 486, 490-491 (1917).

The doctrine captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues. Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg., 545 U.S. 308, 312 (2005) (citing ALI, Study of the Division of Jurisdiction Between State and Federal Courts 164-166 (1968)).

There is no bright-line rule when it comes to exercising federal jurisdiction. Exploring the outer reaches of 28 U.S.C. §1331 requires careful judgments about the nature of the federal interest at stake. See Grable, 545 U.S. at 317 (quoting Merrell Dow Pharmaceuticals Inc. v. Thompson, 478 U.S. 804, 810 (1986)). The question is "does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain

without disturbing any congressionally approved balance of federal and state judicial responsibilities." Grable, 545 U.S. at 314.

"In assessing the substantiality of a purported federal interest, courts assess the extent to which exercise of jurisdiction is consistent with Congressional intent, and look to whether the underlying federal issue is sufficiently 'substantial' to demonstrate a clear indication of 'a serious federal interest in claiming the advantages thought to be inherent in a federal forum." Pennsylvania v. Eli Lilly & Co., 511 F.Supp.2d 576, 583 (E.D.Pa. 2007).

Federal jurisdiction will lie if three conditions are met: (1) the case necessarily raises a federal issue, (2) the federal issue is substantial and in actual dispute, and (3) the exercise of federal jurisdiction will not disturb "any congressionally approved balance of federal and state judicial responsibilities." Grable, 545 U.S. at 314.

In the present case, all three conditions are clearly met and establish jurisdiction in this forum.

IV. ARGUMENT

A. Plaintiff's Complaint Raises a Federal Issue

The crux of the Plaintiff's Complaint is that the Product contained a synthetic form of DMAA which allegedly made the Product "adulterated" under the FDCA and allegedly unlawfully on the market as a dietary supplement, and that Plaintiff's decedent's consumption of the Product led to her death. As the FDA has only recently initiated the administrative review of the topic at issue in this litigation and is in discussions with Defendant, as well as the dietary supplement industry, regarding this precise issue, there can be no questions that this assertion raises a federal issue under the FDCA. See Exhibits "A" and "B".

B. The Federal Issue is Substantial

Despite Plaintiff's downplaying of the unequivocal role that the FDCA and the FDA play in this case, the Complaint makes clear that the Defendants' alleged violation of the FDCA is central to the Plaintiff's claims that Defendants breached their duty of care.

The terms "dietary supplement" and "dietary ingredient" are defined by 21 U.S.C. § 321(ff). Plaintiff alleges that the statute was violated because Defendants allegedly used a synthetic form of DMAA in the Product, thus allegedly making the Product "adulterated" and unlawfully marketed as a dietary supplement in violation of the FDCA. Plaintiff further alleges that the synthetic form of DMAA makes the Product unreasonably dangerous and that Defendants failed to warn about the dangers to consumers. Thus, the central issue of evidence and law in this case surrounds the interpretation and application of the FDCA, which is the subject of a present and ongoing administrative review by the FDA and for which the FDA has not yet completed its administrative process enough to have made any determination, or issue any guidelines or regulations.

Plaintiff disingenuously argues that Defendants "cherry-picked a portion of the Complaint in an attempt to show that violations of the FDCA are the gravamen of Plaintiff's claims." To the contrary, this clear federal question is no mere cherry, but the very core of the Plaintiff's Complaint that Defendants marketed an "illegal" dietary supplement. That is the sole basis for the Plaintiff's claim that the Defendants were negligent and breached their warranty to the Plaintiff's decedent.

Plaintiff relies on Judge Rufe's decision in In re: Avandia Marketing to support its contention that the Court lacks subject matter jurisdiction over this matter. 2012 U.S. Dist.

LEXIS 48319 (E.D.Pa. 2012). Plaintiff's comparison of its complaint to the In re: Avandia Marketing case oversimplifies the allegations at hand and ignores its own well pled complaint.

In In re: Avandia Marketing, the plaintiffs sued the defendants for fraudulently misrepresenting the benefits and safety of Avandia and encouraging physicians to prescribe Avandia over safer, less expensive drugs. In the complaint, the plaintiffs alleged that the FDA had cited the defendants for violations of the FDCA in connection with its marketing of Avandia. Id. at *14. The defendants argued that there was federal jurisdiction over the case because the complaint included allegations of the FDA citations. The Court found that the citations by the FDA were possible evidence of tortious behavior, but did not create a cause of action to permit federal jurisdiction over the case. Id.

Plaintiff alleges that the present case is analogous to the facts of In re: Avandia Marketing, but it is clear that the cases are quite distinct. In In re: Avandia Marketing, the plaintiffs could have presented their claims of fraudulent misrepresentation without requiring the court to analyze the FDCA and determine whether it was violated. Those parties simply argued that the FDA citations were evidence of tortious behavior.

The In re: Avandia Marketing decision is therefore distinguishable as the product at issue in the In re: Avandia Marketing decision had already been through the FDA administrative review process, which resulted in guidelines and/or regulations being issued by the FDA that then resulted in a citation issued by the FDA to that company. In that case, the federal process was complete. Contrarily, in the present case, the administrative review process and discussions with the FDA are presently ongoing and are in their infancy. Remand of this case would therefore cause a state court to hear and decide an ongoing matter before the FDA.

The clear pleading of the Complaint reveals that Plaintiff's claims of negligence, products liability and breach of warranty directly turn on the court's analysis of the FDCA and whether the court concludes that the form of Dimethylamylamine used in the Product was synthetic, was a lawful or unlawful "dietary ingredient" under federal law and was lawfully or unlawfully marketed as a dietary supplement under the FDCA. At this stage of the FDA administrative process, this would effectively require the state court to make determinations on federal law that the FDA has not even made yet nor finished its administrative process on. Clearly, Plaintiff's Complaint asks the court to take on a detailed and complex analysis of the FDCA quite distinct from the case presented in In re: Avandia Marketing.

Thus, the present case involves a substantial federal issue and the court has jurisdiction over this matter.

C. The Federal Issue is In Actual Dispute

There can be little question that the federal issue here is "in actual dispute" and appropriate for federal review. Indeed, there is an ongoing administrative review by the FDA on this precise topic. The ongoing comment stage of the administrative review reveals that the dietary supplement industry, Defendants, as well as at least two United States Senators and fourteen United States Representatives, maintain that Dimethylamylamine (and thus the Product) is appropriately characterized as a "dietary ingredient" for use in a dietary supplement under the FDCA, thus appropriately labeled and lawfully marketed. Again, remand would cause a state court to determine an ongoing federal administrative review and regulatory issue. Thus, the safety of DMAA and its inclusion in dietary supplements is a currently disputed federal issue and appropriate for determination by a federal forum.

D. The Balance of Federal and State Judicial Responsibilities

As stated above, the issue of using DMAA in dietary supplements is a currently disputed federal issue that is in the process of being resolved by the United States Food and Drug Administration, the expert federal agency charged by federal statutes with the responsibility for resolving the matter. Thus, it is appropriate for this court to exercise jurisdiction over this case and will not disturb the balance between federal and state judicial responsibilities. In fact, the use of DMAA in dietary supplements is "a serious federal interest . . . claiming the advantages thought to be inherent in a federal forum." Pennsylvania v. Eli Lilly & Co., 511 F.Supp.2d 576, 583 (E.D.Pa. 2007). Thus, federal jurisdiction over this case will help ensure uniformity regarding the characterization of dietary supplements in the future.

V. CONCLUSION

Based on the foregoing, Defendants respectfully submit that this Court has jurisdiction over the present case and requests that Plaintiff's Motion to Remand be denied.

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